



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,186	05/09/2000	JYUNJI YOSHII	07898-056001	6553

7590 11/14/2002
FISH & RICHARDSON
4350 LA JOLLA VILLAGE DRIVE
SUITE 500
SAN DIEGO, CA 92122

EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
----------	--------------

1634

DATE MAILED: 11/14/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,186

Applicant(s)

YOSHII ET AL.

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,8,10-19 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,8,10-19 and 21-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1634

FINAL ACTION

1. This action is in response to papers filed 30 August 2002 in Paper No. 9 in which claims 1, 3-5, 8, 10, 13, 18, 19, 21 and 22 were amended, claims 2, 6, 7, 9 and 20 were canceled and claims 23-28 were added. All of the amendments have been thoroughly reviewed and entered.

The previous objections and rejections under 35 U.S.C. 112, second paragraph in the Office Action of Paper No. 7 dated 18 April 2002 are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 102 (e) are maintained. All of the arguments have been thoroughly reviewed and are discussed below. New grounds for rejection necessitated by the amendments are discussed.

Claims 1, 3-5, 8, 10-19 and 21-28 are under prosecution.

Information Disclosure Statement

2. The reference listed on the 1449 received 21 June 2002 has been reviewed and considered. A copy of the signed 1449 is enclosed with this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1634

4. Claims 26 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is indefinite for the recitation "the storage medium and associating it with the information on biopolymers" because "associating it with" is a non-specific relational phrase. Therefore, the relationship between the storage medium and the biopolymers is undefined. It is suggested that Claim 26 be amended to define the relationship.

Claim 28 is indefinite for the recitation "IC" because the recitation is an abbreviation the meaning of which may change over time. It is suggested that Claim 28 be amended to replace the abbreviated phrase with the complete phrase.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Art Unit: 1634

6. Claims 1, 3-5, 8, 10-19, 21-24, 26 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Nova et al (U.S. Patent No. 6,284,459 B1, filed 5 September 1996).

Regarding Claim 1, Nova et al disclose a biochip comprising a surface spotted with a plurality of biopolymers in a predetermined pattern i.e. matrix and a storage medium for storing information of the biopolymers to be spotted i.e. memory (Column 7, lines 6-65 and Fig. 22-30) wherein the storage medium stores information comprising spot location, identity of the biopolymers spotted on each spot location and the amount of biopolymers spotted on each spot (Column 8, lines 42-47; Column 14, lines 47-65; Column 23, lines 47-56; and Column 91, line 50-Column 92, line 7).

Regarding Claim 3, Nova et al disclose the biochip wherein the surface and the storage medium are detachable i.e. the memory and matrix are pressed to fit into the well and are therefore detachable (Column 41, line 55-Column 42, line 8 and Fig. 22-30).

Regarding Claim 4, Nova et al disclose the biochip wherein the surface and the storage medium are formed integrally i.e. the memory and matrix are bonded into the well and are therefore formed integrally (Column 41, line 55-Column 42, line 8 and Fig. 22-30).

Regarding Claim 5, Nova et al disclose the biochip wherein the storage medium comprises a semiconductor memory which can read/write information in a non-contact state (Column 57, lines 28-58).

Regarding Claim 8, Nova et al disclose a method of using a biochip comprising applying a sample to the biochip wherein the biochip comprises a surface spotted with a plurality of biopolymers in a predetermined pattern; detecting a spot location where the sample has bound wherein the biochip comprises a storage medium that stores information of spot locations in relation to information of spotted biopolymers; and storing a displaying information of the biopolymer that has bound with a sample by searching the data stored in the storage medium based on the spot location bound with sample molecule (Column 14, lines 47-65) wherein the storage medium stores information comprising spot location, identity of the biopolymers

Art Unit: 1634

spotted on each spot location and the amount of biopolymers spotted on each spot (Column 8, lines 42-47; Column 14, lines 47-65; Column 23, lines 47-56; and Column 91, line 50-Column 92, line 7).

Regarding Claim 10, Nova et al disclose the biochip wherein the storage medium further comprises a covered surface (Column 31, lines 40-45 and Column 32, lines 22-38).

Regarding Claim 11, Nova et al disclose the covered surface comprises a plastic or glass (Column 31, lines 40-45 and Column 32, lines 22-38).

Regarding Claim 12, Nova et al disclose the covered surface protects the storage medium for exposure to a solution (Column 32, lines 22-27).

Regarding Claim 13, Nova et al disclose the biochip further comprising a semiconductor memory support (Column 50, lines 34-45).

Regarding Claim 14, Nova et al disclose the biochip wherein the semiconductor memory support comprises a silicon wafer i.e. chip (Column 19, lines 63-67).

Regarding Claim 15, Nova et al disclose the semiconductor memory support is covered (Column 32, lines 22-38).

Regarding Claim 16, Nova et al disclose the semiconductor memory support is covered with a resin i.e. agarose (Column 32, lines 32-38).

Regarding Claim 17, Nova et al disclose the semiconductor memory support is the surface spotted with the biopolymer (Column 8, lines 58-62 and Column 19, lines 63-67).

Regarding Claim 18, Nova et al disclose the biochip wherein the biopolymer comprises DNA (Column 24, lines 8-19).

Regarding Claim 19, Nova et al disclose the biochip wherein the biopolymer comprises a protein (Column 24, lines 8-19).

Regarding Claim 20, Nova et al disclose the biochip wherein the information stored in the storage medium comprises the amount of biopolymer (Column 14, lines 54-60).

Art Unit: 1634

Regarding Claim 21, Nova et al disclose the method of Claims 7 and 8 wherein the biopolymer comprises DNA (Column 24, lines 8-19).

Regarding Claim 22, Nova et al disclose the method of Claims 7 and 8 wherein the biopolymer comprises a protein (Column 24, lines 8-19).

Regarding Claim 23, Nova et al disclose the biochip further comprising a case member (i.e. well) wherein the surface and the storage medium are detachable from the case member i.e. the memory and matrix are pressed to fit into the well and are therefore detachable from the well (Column 41, line 55-Column 42, line 8 and Fig. 22-30).

Regarding Claim 24, Nova et al disclose the biochip further comprising a case member (i.e. well) wherein the surface and the storage medium are formed integrally with the case member i.e. the memory and matrix are bonded into the well and are therefore formed integrally with the well (Column 41, line 55-Column 42, line 8 and Fig. 22-30).

Regarding Claim 26, Nova et al disclose a method of manufacturing a biochip according to Claim 1 comprising: spotting a plurality of biopolymers on a surface of the biochip in a predetermined pattern and writing information of the spot locations to the storage medium and associating it with the information of biopolymers on the spot locations (Column 91, line 15-Column 92, line 14).

Regarding Claim 27, Nova et al disclose a method of using the biochip of Claim 1 comprising: applying a sample to the biochip, detecting a spot location where hybridization of a biopolymer has occurred, searching the storage medium for information on the hybridized biopolymer based on the information about the spot location and displaying the information on the biopolymer that has hybridized (Column 74, lines 36-67; Column 91, line 44-Column 92, line 27; and Column 100, lines 46-63).

Regarding Claim 28, Nova et al disclose the biochip further comprising a looped antenna wherein the storage medium is a IC memory connected to the looped antenna and the

Art Unit: 1634

storage medium being capable of reading/writing information in a non-contact state (Column 68, line 53-Column 69, line 61).

7. Claims 1, 3, 4, 8, 13, 14, 17-19, 21-24, 26 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Perttunen et al (U.S. Patent No. 5,968,728, filed 30 April 1997).

Regarding Claim 1, Perttunen et al disclose a biochip comprising a surface capable of being spotted with a plurality of biopolymers in a predetermined pattern i.e. a first member having a plurality of sites (Column 7, lines 41-47) and a storage medium for storing information of the biopolymers to be spotted i.e. second member (Column 7, lines 55-58 and Fig. 11 and 12).

Regarding Claim 3, Perttunen et al disclose the biochip wherein the surface and the storage medium are detachable (Column 7, lines 48-54 and Fig. 12).

Regarding Claim 4, Perttunen et al disclose the biochip wherein the surface and the storage medium are formed integrally i.e. formed of a unitary member (Column 7, lines 48-54).

Regarding Claim 8, Perttunen et al disclose a method of using a biochip comprising applying a sample to the biochip wherein the biochip comprises a surface spotted with a plurality of biopolymers in a predetermined pattern (Column 7, lines 55-58); detecting a spot location where the sample has bound wherein the biochip comprises a storage medium that stores information of spot locations in relation to information of spotted biopolymers; and storing a displaying information of the biopolymer that has bound with a sample by searching the data stored in the storage medium based on the spot location bound with sample molecule (Column 8, lines 20-54).

Art Unit: 1634

Regarding Claim 13, Perttunen et al disclose the biochip further comprising a semiconductor memory support (Column 4, lines 42-47 and 62-65).

Regarding Claim 14, Perttunen et al disclose the semiconductor memory chip comprises silicon (Column 4, lines 42-47).

Regarding Claim 17, Perttunen et al disclose the semiconductor memory support is the surface spotted with the biopolymer (Column 4, lines 42-51).

Regarding Claim 18, Perttunen et al disclose the biochip wherein the biopolymer comprises DNA (Column 1, lines 36-45).

Regarding Claim 19, Perttunen et al disclose the biochip wherein the biopolymer comprises a protein (Column 4, lines 24-26).

Regarding Claim 21, Perttunen et al disclose the method of Claims 8 wherein the biopolymer comprises DNA (Column 1, lines 36-45).

Regarding Claim 22, Perttunen et al disclose the method of Claims 8 wherein the biopolymer comprises a protein (Column 4, lines 24-26).

Regarding Claim 23, Perttunen et al disclose the biochip further comprising a case member (i.e. package) wherein the surface and the storage medium are detachable from the case member (Column 7, lines 48-54 and Fig. 12).

Regarding Claim 24, Perttunen et al disclose the biochip further comprising a case member wherein the surface and the storage medium are formed integrally with the case member i.e. formed of a unitary member (Column 7, lines 48-54).

Regarding Claim 26, Perttunen et al disclose a method of manufacturing a biochip according to Claim 1 comprising: spotting a plurality of biopolymers on a surface of the biochip in a predetermined pattern and writing information of the spot locations to the storage medium and associating it with the information of biopolymers on the spot locations (Abstract, Column 2, line 48-Column 3, line 31 and Fig. 1).

Art Unit: 1634

Regarding Claim 27, Perttunen et al disclose a method of using the biochip of Claim 1 comprising: applying a sample to the biochip, detecting a spot location where hybridization of a biopolymer has occurred, searching the storage medium for information on the hybridized biopolymer based on the information about the spot location and displaying the information on the biopolymer that has hybridized (Column 5, lines 13-20 and Column 8, lines 20-54).

8. Claims 1, 5 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Zeleny et al (U.S. Patent No. 6,215,894 B1) in view of Nova (U.S. Patent No. 6,284,459, filed 5 September 1996).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Regarding Claim 1, Zeleny et al disclose a biochip comprising a surface capable of being spotted with a plurality of biopolymers in a predetermined pattern i.e. array and a storage medium for storing information of the biopolymers to be spotted i.e. barcode (Column 2, line 66-Column 3, line 7 and Fig. 1-2).

Regarding Claim 5, Zeleny et al disclose the biochip wherein the storage medium comprises a semiconductor memory which can read/write information in a non-contact state (Column 3, lines 25-30).

Regarding Claim 8, Zeleny et al disclose a method of using a biochip comprising applying a sample to the biochip wherein the biochip comprises a surface spotted with a plurality of biopolymers in a predetermined pattern; detecting a spot location where the sample has bound wherein the biochip comprises a storage medium that stores information of spot locations in relation to information of spotted biopolymers; and storing a displaying information

Art Unit: 1634

of the biopolymer that has bound with a sample by searching the data stored in the storage medium based on the spot location bound with sample molecule (Column 2, lines 13-32).

Response to Arguments

9. Applicant argues that Nova et al Perttunen et al and Zeleny et al do not teach or suggest storing the amount of biopolymer spotted at each spot in a storage medium and they do not teach a storage medium that stores information comprising spot location, identity of the biopolymers spotted on each spot location and the amount of biopolymers spotted on each spot location. Therefore, Applicant argues, the references do not teach or suggest every limitation of the claimed invention. The argument has been considered but is not found persuasive for several reasons. First, Nova et al clearly teach the storage medium stores information regarding spot location and the identity and amount of the biopolymers (Column 8, lines 42-47; Column 14, lines 47-65; Column 23, lines 47-56; and Column 91, line 50-Column 92, line 7). Second, the claims are drawn to a biochip comprising a surface spotted with a plurality of biopolymers and a storage medium "for storing information". The recitation "for storing information" is a recitation of intended use. The recitation of an intended use does not define or limit the structure of the storage medium. As such, the claims are drawn to a biochip comprising a surface and a storage medium.

A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Art Unit: 1634

Finally, Nova et al Perttunen et al and Zeleny et al each teach a biochip comprising a surface spotted with a plurality of biopolymers and a storage medium. Therefore, Nova et al Perttunen et al and Zeleny et al disclose the invention as claimed.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nova et al (U.S. Patent No. 6,284,459 B1, filed 5 September 1996) in view of Fodor et al (U.S. Patent No. 5,800,992, issued 1 September 1998).

Regarding Claim 25, Nova et al teach the biochip comprising a surface spotted with a plurality of biopolymers in a predetermined pattern i.e. matrix and a storage medium for storing information of the biopolymers to be spotted i.e. memory (Column 7, lines 6-65 and Fig. 22-30) wherein the storage medium stores information comprising spot location, identity of the biopolymers spotted on each spot location and the amount of biopolymers spotted on each spot (Column 8, lines 42-47; Column 14, lines 47-65; Column 23, lines 47-56; and Column 91, line 50-Column 92, line 7) wherein the biochip comprises arrayed spots of high density (Column 7, lines 12-50) but they do not specifically teach a density of 10,000 spot/cm². However, arrayed spots of high density wherein the density is about 10,000 spot/cm² were well known in the art at the time the claimed invention was made as taught by Fodor et al (Column 20, lines 27-39). Furthermore, Fodor et al teach that high density arrays (e.g. 10,000 spot/cm²) were preferred

Art Unit: 1634

in methods for assaying biopolymer binding because they reduce the number of assays necessary and thereby increase the speed and accuracy of assay procedures and results (Column 2, lines 26-47). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the high density array of Fodor et al (e.g. 10,000 spot/cm²) to the arrayed biomolecules of Nova et al thereby providing a biochip which reduces the number of assays for the expected benefits of increased speed and accuracy of assay procedures and results as taught by Fodor et al (Column 2, lines 26-47).

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

13. No claim is allowed.

Art Unit: 1634

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
November 13, 2002